2 Windsor Framework: substances of human origin[5]

This EU document is politically important because:

- it applies to Northern Ireland (NI) under the terms of the Windsor Framework and has implications for Great Britain (GB);
- any divergence between GB and NI as well as the EU could have implications for patients in NI reliant on GB, and patients in GB reliant on the EU in some circumstances; and
- the Government is considering whether to introduce similar changes, subject to ongoing analysis and discussion with the UK's devolved governments under the relevant Common Frameworks.

Action

- Write to the Minister seeking a further update.
- Draw to the attention of the Health and Social Care Committee, the Northern Ireland Affairs Committee, the Welsh Affairs Committee and the Scottish Affairs Committee.

Overview

2.1 The EU has legislation[6] in place setting minimum safety requirements for blood, tissues and cells (the EU 'BTC Directives'). As they are over twenty years old, the European Commission has proposed to update them through a replacement draft Regulation which will apply to NI under the terms of the Windsor Framework. It will have implications for NI directly but also for the rest of GB, as NI is heavily reliant on GB for the supply of these products and some are sourced from the EU to treat GB patients.

2.2 The Commission proposed broadening the coverage to include all 'Substances of Human Origin' (SoHO),[7] therefore including previously-excluded types (such as human breast milk and intestinal microbiota). The draft Regulation provides measures to ensure safety and quality for patients treated with SoHO therapies and fully protect them from avoidable risks. We set out further details of the draft Regulation in our Report of 26 October 2022.

2.3 We wrote to the Government on 26 October 2022, raising a number of queries. First, we asked the Government to set out their plans for retained EU law[8] affecting SoHO, noting the provisions of the Retained EU Law (Revocation and Review) Bill. Second, we asked about elements of the draft Regulation which may not be relevant to the UK as a

5 Proposal for a Regulation on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC AND 2004/23/EC; COM (2022) 338; Legal base: -; Department: Health and Social Care; Devolved Administrations: Consulted; ESC number: 42110.

6 Directive 2002/98/EC ('Blood Directive') and Directive 2004/23/EC ('Tissues and Cells Directive')

7 Any substance collected from the human body in whatever manner, excluding organs.

8 EU law retained in domestic law following the UK's withdrawal from the EU.

third country, including the possibility that delegations of inspectors from EU Member States would have the right to inspect Northern Irish SoHO establishments. Third, we noted the broader scope of the draft Regulation compared to the BTC Directives and asked whether the entirety of the draft Regulation should apply automatically in NI. Finally, we requested information on intra-UK discussions about the policy implications of the draft Regulation.

2.4 The Minister of State (Will Quince MP) replied to us on 7 December 2022. Our consideration of the Minister's letter was delayed pending our scrutiny of the Windsor Framework agreement. In his letter (see below for more details), the Minister confirmed that the SoHO legislation was part of the review of retained EU law being undertaken and that maintaining patient safety and public health would remain paramount during that process. The Minister also confirmed that delegations of EU Member State officials would be able to inspect Northern Irish SoHO establishments, but he noted that this was already permissible under the terms of the Windsor Framework. Northern Ireland should have access to the coordination mechanisms set up under the draft Regulation, said the Minister. Finally, the Minister confirmed that the implications of the draft Regulation across the UK were being discussed among the four nations.

2.5 We have responded to the Minister welcoming the Government's overall approach, which prioritises patient safety across the UK and requesting information on the outcome of the UK-wide assessment in due course.

UK Government position

Retained EU Law

2.6 The Minister noted that the Retained EU Law (Revocation and Reform) Bill would, subject to Parliamentary approval, "enable the Government to realise the benefits of Brexit by adopting a regulatory approach which best meets the UK's interests." The Government, he said, was reviewing how best to use the powers provided by the Bill, including which instances of retained EU law should be repealed, reformed or preserved. This included considering the SoHO legislation[9] that is retained EU law and relevant separation agreement law, for the purposes of implementing the Windsor Framework.

2.7 Maintaining high quality and safety standards and maximising patient access to substances of human origin (SoHO) is, said the Minister, a priority. As such, any reforms would not come at the expense of the UK's already high standards. Maintaining patient safety and public health would remain paramount when reforming retained EU law and the Government would continue to work with a wide range of organisations and stakeholders to ensure the best possible outcome.

9 The Blood Safety and Quality Regulations 2005/50; The Quality and Safety of Organs Intended for Transplantation Regulations 2012/1501; The Human Tissue (Quality and Safety for Human Application) Regulations 2007/1523; and The quality and safety provisions in the Human Fertilisation and Embryology Act 1990.

Windsor Framework

2.8 The Minister confirmed that, under the Windsor Framework,[10] the draft Regulation will become directly applicable in NI. Secondary legislation will need to be made under the European Union (Withdrawal) Act 2018 to revoke the existing legislation implementing the BTC Directives in NI, as well as to deal with enforcement of the draft Regulation. The Government was working on the basis that the full scope of the draft Regulation will be applicable in NI.

2.9 The Minister confirmed that inspections of SoHO establishments (those processing and storing SoHO) and SoHO entities (those doing other SoHO activities), as well as third country suppliers must take place. These could take place jointly at the request of one or more Competent Authorities (CAs), and the Member State (or NI) must make reasonable efforts to enable this. The Minister noted that similar requirements were already in place in relation to inspections of tissue establishments, so this was not a new concept.

2.10 Additionally, said the Minister, Article 12(2) of the Windsor Framework already allows for EU representatives to have the right to be present when the UK is implementing and applying the Windsor Framework, and the UK must facilitate access.

2.11 Concerning access to the SoHO Platform and membership of the SoHO Coordination Board, the Minister said that the draft Regulation allows for Member State and the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) experts to be on the Board. He considered that experts from NI may be able to apply to be a member of the SoHO Coordination Board, given their vast expertise in transfusion and transplantation. United Kingdom EDQM members may also be invited to participate. Once the draft Regulation's final text is agreed and adopted, the Government would be writing to the Commission to confirm if this is the case. NI may also have access to the EU SoHO platform, he said, as this is needed to fulfil their legal obligations.

Implications for Great Britain

2.12 The Minister said that the Government was reviewing the draft Regulation and, following stakeholder consultation and an options analysis, decisions would be made as to whether to introduce similar changes in GB. Decisions would take into account a number of factors including: patient safety; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health disparities. The Government would provide a summary of the outcome of its assessment in due course.

2.13 The Minister noted that legislative competence for the donation, processing and use in treatment of human reproductive cells remains reserved to Westminster while competence in respect of all other human tissues and cells, blood and organs is devolved. The two SoHO Common Frameworks cover the areas of devolved competence. However, close working continues between the UK Government and the devolved governments on reserved and excepted matters that impact significantly on devolved responsibilities.

2.14 The Common Frameworks in this area aim to maintain a compatible minimum set of safety and quality standards between the UK Government, Scottish Government, Welsh

10 The Minister's letter refers to the "Ireland/Northern Ireland Protocol" but, since then, the EU and UK have agreed to refer to the Protocol as the 'Windsor Framework'. The amendments made to the original Protocol by the Windsor Framework agreement do not affect application of this draft Regulation to NI.

Government and the NI Executive and make it easier for blood, organs, tissues and cells to continue to be shared across the UK. The underlying principle, explained the Minister, is that administrations agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and allowing sufficient scope for UK-wide discussion and decision making.

2.15 Finally, noted the Minister, under the SoHO Frameworks process, officials (across the four governments) were continuing to meet regularly to discuss policies that may impact each other, including the EU SoHO Regulation. As the Regulation progresses through the EU processes, further discussions and stakeholder consultation would take place to fully consider the impact on the existing safety and quality standards in this area.

Our assessment

2.16 We have expressed concerns about amendments made to the Retained EU Law (Revocation and Reform) Bill during its passage through Parliament. These changes, we have said, fundamentally undermine the purpose of the Bill. That said, we have always recognised that some EU measures retained in the UK post-Brexit are valuable. Measures such as the BTC Directives are good examples of this, although these measures as retained in the UK merit some reform, just as the European Commission has reviewed the original EU Directives and tabled its draft replacement Regulation. The Retained EU Law (Revocation and Reform) Bill will allow relevant changes to be made, which we welcome.

2.17 Like the Government, we agree that maintaining patient safety must be the paramount objective. We welcome the intra-UK work that is ongoing around the draft Regulation, based on the view that a similar approach should be taken across the UK. Given that NI must maintain alignment with EU law in this area, that means that the draft Regulation will be the basis for developments across the UK. As a consequence, we take a particular interest in both EU-level discussions on the Regulation and in intra-UK discussions.

2.18 Since the Minister wrote, the UK and EU agreed a revised approach to implementing what was formerly known as the Ireland/Northern Ireland Protocol and is now known as the Windsor Framework. While the agreement has no impact on the application of this legislation in NI, nor its potential implications for the rest of the UK, it does strengthen consultation arrangements. The Windsor Framework allows for the creation of structured expert groups to allow detailed UK-EU discussion of new rules applied under the Windsor Framework across the full range of issues. A new emergency brake mechanism, known as the 'Stormont Brake' was also introduced to be used in exceptional circumstances to prevent the automatic alignment of NI's law with changes to certain EU laws. We set out more details about the Windsor Framework in our Report of 24 May 2023.

2.19 Deliberations are ongoing in the EU institutions on this draft Regulation, with few concrete developments expected for several months. We will request an update by mid-October 2023 on those developments and on engagement between the UK and EU, particularly following the adoption of enhanced arrangements under the Windsor Framework agreement.

Action

2.20 We have written to the Minister of State as set out below.

2.21 We are reporting this document to the House as politically important and we draw it to the attention of the Health and Social Care Committee, the Northern Ireland Affairs Committee, the Welsh Affairs Committee and the Scottish Affairs Committee.

Letter from the Chair to the Minister of State (Will Quince MP)

We considered your letter of 7 December 2022 on the above draft Regulation at our meeting of 21 June 2023. Our consideration was delayed pending our scrutiny of the Windsor Framework agreement.

Since you wrote, there have been a number of important developments salient to this draft Regulation, including amendments to the Retained EU Law (Revocation and Review) Bill as well as the adoption of the Windsor Framework agreement, further to which the Government signalled that the NI Protocol Bill would not be enacted.

Like you, we agree that maintaining patient safety must be the paramount objective behind policy in this area. We welcome the intra-UK work that is ongoing around the draft Regulation, based on the view that a consistent approach should be applied across the UK. Given that NI must maintain alignment with EU law in this area, the effect is that the draft Regulation will be the basis for policy developments across the UK. As a consequence, we take a particular interest in both EU-level discussions on the Regulation and in intra-UK discussions.

We would welcome an update on the progress of both EU level and intra-UK discussions by 16 October 2023. We also look forward to receiving the outcome of the Government's UK-wide assessment, to which you referred. Noting the enhanced arrangements agreed under the Windsor Framework for UK-EU cooperation on draft EU legislation, it would also be helpful if you could set out how you are engaging with the EU on this draft Regulation.

2 Northern Ireland Protocol: Substances of Human Origin[48]

This EU document is politically important because:

- It applies to Northern Ireland (NI) under the terms of the Northern Ireland Protocol and has implications for Great Britain (GB);
- The Minister acknowledges that divergence between GB and NI as well as the EU could have implications for patients in NI reliant on GB, and patients in GB reliant on the EU in some circumstances; and
- The Government is considering whether to introduce similar changes, subject to ongoing analysis and discussion with the UK's devolved governments.

Action

- Write to the Minister seeking further information.
- Draw to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

Overview

2.1 In the wake of contaminated blood scandals[49] in the 1980s and 1990s—which saw thousands of patients in the EU, then including the UK, infected with HIV and hepatitis by blood and plasma-derived medicinal products—the EU adopted legislation[50] setting minimum safety requirements for blood, tissues and cells (the 'BTC Directives'). The BTC Directives are, however, twenty years old and so the Commission is proposing to update them through a replacement Regulation which will apply to Northern Ireland (NI) under the terms of the NI Protocol. It will have implications for NI directly but also for the rest of GB as NI is heavily reliant on GB for the supply of these products and some are sourced from the EU to treat GB patients.

2.2 Based on an evaluation[51] in 2019 of the BTC Directives, the Commission has proposed broadening the coverage to include all Substances of Human Origin (SoHO),[52] therefore including previously-excluded types (such as human breast milk and intestinal microbiota). The proposal provides measures to ensure safety and quality for patients treated with SoHO therapies and fully protect them from avoidable risks. The proposal also aims to facilitate the development of safe and effective, innovative SoHO therapies.

48 Proposal for a Regulation on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC AND 2004/23/EC; COM (2022) 338; Legal base: ; Department: Health and Social Care; Devolved Administrations: Consulted; ESC number: 42110.

49 Factor 8, 'What is the contaminated blood scandal?' [Accessed 30 September 2022].

50 Directive 2002/98/EC ('Blood Directive') and Directive 2004/23/EC ('Tissues and Cells Directive')

51 European Commission, 'Executive Summary of the Evaluation of the Union legislation on blood, tissues and cells', SWD (2019) 376, 10 October 2019.

52 Any substance collected from the human body in whatever manner, excluding organs.

Recognising that the existing legislation has failed to respond to technical and scientific developments, the draft Regulation provides mechanisms to easily, but safely, update safety and quality standards.

2.3 In his Explanatory Memorandum, (EM) the then Minister of State (Rt Hon. Robert Jenrick MP) confirmed applicability of the legislation (once adopted) to NI. He observed that it is likely to be beneficial for NI as it aims to boost the safety and quality of SoHO. Noting that NI 'has a reliance' on the import of SoHO from GB, the Minister said that significant divergence between GB and NI may cause disruption to supply and limit NI's ability to import much needed SoHO from GB. The Government, said the Minister, is currently reviewing the Commission's proposal, and a decision will be taken in due course as to whether to introduce similar changes in GB. The Minister noted in his EM that elements of the policy are reserved to the UK Parliament and elements are devolved. The Government will therefore work with the UK's other devolved governments through the relevant Common Frameworks to maintain compatible minimum standards across the UK.

2.4 We have identified a number of issues on which we would welcome further information, as set out in the letter at the end of this chapter.

Commission proposal

2.5 An evaluation[53] in 2019 of the BTC Directives found that they have brought very good levels of overall safety and quality in these sectors but that:

- patients are not fully protected from avoidable risks due to out-of-date technical rules;
- blood, tissues and cells (BTC) donors and children born from donated eggs, sperm or embryos (offspring) are exposed to avoidable risks;
- Member States have divergent approaches to oversight that hampers cross-border exchanges of BTC;
- full potential of BTC processed or used in new ways is not reached for patients; and
- patients are vulnerable to interruptions in EU supply of BTC.

2.6 To improve harmonisation, ensure a uniform level of protection across the EU and simplify cross-border exchange and access of SoHO therapies, the Commission proposes to repeal the Directives and replace them with a single Regulation that will be equally applicable in all Member States. Member States may still add more stringent requirements, in particular to ensure alignment to the set-up of national healthcare systems.

2.7 Broadly, the draft Regulation promotes innovation and provides better protection for patients, donors and offspring.[54]

53 European Commission, 'Executive Summary of the Evaluation of the Union legislation on blood, tissues and cells', SWD (2019) 376, 10 October 2019.

54 European Commission, 'European Health Union: Stronger rules for greater safety and quality of blood, tissues, and cells', 14 July 2022.

2.8 To provide better protection, the draft Regulation covers all substances of human origin, except solid organs, and it extends rigorous safety and quality standards to SoHO donors and to children born from donated eggs, sperm or embryos. This reflects, for example, the evolution of human fertilisation technology since the Tissues and Cells Directive was adopted.

2.9 The Commission may adopt implementing acts to support implementation of the high-level standards set out in the text. Where there are no such implementing acts, professionals should, to meet these standards, apply safety and quality guidelines developed by the European Centre for Disease Prevention and Control (ECDC)[55] and the European Directorate for the Quality of Medicines & HealthCare (EDQM).[56] There is some flexibility for professionals to apply other, equivalent, guidelines accepted by national authorities and demonstrated as achieving equivalent standards of safety and quality. In the absence of a technical guideline from expert bodies, establishments can set their own technical method taking into account internationally recognised standards, scientific evidence and a documented risk assessment. The Commission says that this flexible approach will facilitate "an efficient and responsive implementation of safety and quality standards whenever risks and technologies change" and will limit the need for further EU legislation. Among measures to strengthen national oversight, the draft Regulation includes provision for joint inspections of SoHO establishments undertaken by inspectors from several Member States.

2.10 To promote innovation, the draft Regulation introduces: a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring; registration of all entities carrying out activities affecting safety and quality of SoHO; and the establishment of a SoHO Coordination Board (SCB) to support a common implementation of the new Regulation.

2.11 The draft Regulation proposes measures to improve the resilience of the sector, mitigating risk of shortage. This includes the requirement for SoHO entities to report their annual activity data and the establishment of an EU SoHO Platform to facilitate effective and efficient exchange of information, such as serious adverse occurrences related to SoHO and insufficiencies of supply.

UK Government position

2.12 The Minister confirmed that, once adopted, the Regulation will apply in NI as it replaces legislation already listed in the Northern Ireland Protocol. He added that the NI Executive has a particular interest in the proposal. The Minister judged that the new Regulation is likely to "have an overall positive impact on the SoHO sector in NI" given the proposal's objective to increase safety, quality, innovation and supply of SoHO.

2.13 The Minister warned that the inclusion of updates to minimum safety and quality standards under the Commission's proposals may introduce divergence between GB and

55 The ECDC is an EU agency of which the UK is no longer a part, although the ECDC works closely with third countries. It develops and updates guidelines on safety and quality of SoHO from a communicable disease threat perspective.

56 The EDQM is a Council of Europe body, of which the UK remains a part. It develops and updates guidelines on safety and quality of blood, tissues and cells.

NI; and between GB and EU Member States. This divergence, he said, would only occur once the proposals are in force in NI and the EU, and if the UK, Scottish and Welsh Governments elected not to voluntarily align with these changes.

2.14 Northern Ireland, said the Minister, has a reliance on import of SoHO from GB, such as blood imports from England for use in patient transfusions. If there is significant divergence between GB and NI, the Minister considered, this may cause disruption to supply and limit NI's ability to import much needed SoHO from GB. Movement from NI to GB is protected by the principle of unfettered access in the Internal Market Act.

2.15 There are also movements between GB and the EU, with some GB establishments continuing to have a strategic supply dependency on some EU Member States for SoHO. The Minister explained that patients often require a match to be able to proceed with their treatment and that, where a match cannot be found in the UK, registers in the EU are also searched. He concluded that it will be important to maintain minimum standards with the EU to allow the movement of NI and EU SoHO which is used in life-saving and life-changing treatments for patients across the UK.

2.16 The Minister explained that the Government is currently reviewing the Commission's proposal, and a decision will be taken in due course as to whether to introduce similar changes in GB. This decision will consider several factors that may be affected by the proposals including: patient safety; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health inequalities.

2.17 Concerning possible voluntary alignment by GB, the Minister noted that UK regulators made recommendations to the EU as part of the consultation on, and evaluation of, the BTC Directives. Given that these recommendations fed into the development of the SoHO Regulation, the Minister considered it likely that, for GB, external stakeholders will support voluntary alignment with the minimum safety and quality standards included in the Commission's proposal. Certain elements of the proposal, such as encouraging Member State collaboration, would be unsuitable for GB to implement since the UK is no longer an EU Member State, and they are unlikely to affect the maintenance of equivalent safety and quality standards with the EU and between GB and NI.

2.18 Competence to regulate in this area across the UK is split between the UK Parliament and the devolved legislatures. The Minister explained that policy on reproductive tissues and cells policy is reserved, and that blood and non-reproductive tissues and cells policy is devolved. Across the UK administrations, said the Minister, policy in this area is covered by the Blood Safety and Quality Provisional Common Framework and the Organs, Tissues and Cells Provisional Common Framework. They support the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for blood and non-reproductive tissues and cells. Following the processes set out in both Frameworks, said the Minister, policy decisions may be made in GB to reflect some of the changes proposed by the Commission.

2.19 The Minister observed that the draft Regulation is of a framework nature, delegating certain standards and technical guidance to the EDQM and ECDC, as well as establishing further detail through EU Implementing Acts. The UK Government and devolved

governments will need to undertake further scoping before deciding whether to voluntarily align with new EDQM and ECDS guidelines and will assess the Implementing Acts once there is further information.

2.20 Concerning the increased scope of the legislation to capture all forms of SoHO (beyond just blood, tissues and cells), the Minister considered it unclear what the effect of such change could be in the UK. While the expansion of the scope will automatically apply in NI, this expansion has not been considered by the UK Government and devolved governments previously. Further time and work will be required, said the Minister, to assess whether there is any benefit to voluntarily implementing such a change at a UK-wide level.

2.21 The Minister drew attention to the Northern Ireland Protocol Bill, designed to protect the integrity of the UK, avoid a hard border and safeguard the EU Single Market. He said that the Government had been engaged in consultation over the summer with stakeholders on how the Bill will work in practice, including in the SoHO sector.

Our assessment

2.22 The Commission has proposed this legislation in the light of weaknesses identified in the implementation of the BTC Directives. We note that, when it was an EU Member State, the UK responded to the Commission's consultation on reviewing the legislation and we note the Minister's confidence that the outcome reflects, at least to a degree, the UK's input.

2.23 The BTC Directives were implemented in UK law[57] and the domestic implementing legislation forms part of retained EU law by virtue of the EU (Withdrawal) Act 2018. The Retained EU Law (Revocation and Reform) Bill contains a range of powers to amend, revoke, restate, replace or update retained EU law. Some of the powers cannot, however, be exercised in relation to "Northern Ireland legislation". Given the weaknesses identified by the Commission in its evaluation, and the UK's input, it seems to us likely that the domestic legislation which implemented the BTC Directives would be identified as the type of retained EU law that should be amended or replaced when the Government undertakes its review of that law. Furthermore, the direction of travel proposed by the Commission, at least for blood, tissues and cells may well be broadly in line with changes that the UK may like to see. That being the case and given the importance of ensuring that lifesaving SoHO from EU Member States remains available to UK patients, we agree that there are compelling arguments in favour of adopting an approach broadly in line with that proposed by the Commission.

2.24 The Retained EU Law (Revocation and Reform) Bill must be factored into the Government's work in this policy area. As a default, the sunset mechanism in the Bill

57 Blood Safety and Quality Regulations 2005 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Note these Regulations were amended by EU Exit Statutory Instruments under the EU (Withdrawal) Act 2018 (EUWA): The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 and The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020.; The Human Tissue (Quality and Safety) for Human Application (Amendment) EU Exit Regulations 2019 and The Human Tissue (Quality and Safety) for Human Application) (Amendment) (EU Exit) Regulations 2020. Both sets of 2020 Exit SI Regulations use the section 8C powers under the EUWA to implement the Northern Ireland Protocol. This is to ensure that the EU law as set out in the text of the Directives continues to apply to Northern Ireland, not the retained EU law version (as amended) which applies to the rest of GB.

would operate to revoke the domestic law which implemented the BTC Directives[58] with effect from 31 December 2023. We note that the sunset mechanism does not apply to "Northern Ireland legislation" but that the domestic legislation implementing the BTC Directives which applies in NI does not come within that definition. The effect of that, absent any other regulatory change, would be to leave a regulatory vacuum in this area of public health, which would clearly be undesirable. Moreover, it would also create immediate divergence with NI. To reiterate, as the Minister explained in his EM, this is because under the Northern Ireland Protocol, the Regulation (once adopted) will become directly applicable in NI.[59] The draft Regulation needs to proceed through the EU's decision-making process before it can enter into force and will only apply two years later. We will seek confirmation from the Minister that the Government will, at the very least, extend the sunset mechanism for this legislation as permitted under the Bill and pending finalisation of the EU's Regulation.

2.25 The Government identifies elements of the proposal which may not be relevant to the UK as a third country, such as provisions around cooperation among Member States. In that context, we will seek clarity on whether the Government envisages that the provisions on cooperation—including joint inspections, access to the SoHO Platform and membership of the SoHO Coordination Board—would be applicable to NI. We would be concerned if a delegation of inspectors from EU Member States would have the right to inspect Northern Irish SoHO establishments.

2.26 A further complexity relates to the scope of the measure, which is broader than the BTC Directives. We will seek clarity from the Government as to whether it believes that the entirety of the Regulation should apply automatically in NI. The broader scope inevitably creates potential difficulties for NI if GB does not adopt a similar approach. The Government says that it is assessing the broader scope. We will request a summary of the outcome of that assessment once complete.

2.27 The Government mentions that it is working with stakeholders on the implementation of the Northern Ireland Protocol Bill in this sector. We will monitor with interest the outcome of those discussions as well as the progress of negotiations between the UK and the EU on implementation of the Northern Ireland Protocol. We trust that, for movement of SoHO between GB and NI, patient safety will be the overriding objective.

2.28 Finally, the Government helpfully sets out how the Commission's proposal interacts with two of the common frameworks adopted to support policy-making across the UK following the UK's withdrawal from the European Union. We will seek information from the Government as to the stage at which intra-UK discussions have reached in response to the Commission's proposal. Noting that some of the policy is reserved and some is devolved, any changes to UK legislation replicating the EU rules, particularly under the Retained EU Law (Reform and Revocation) Bill (once enacted), would need to take that into account and require consultation between the different administrations.

58 See footnote 10.

59 He further notes that secondary legislation will need to be made under the EU (Withdrawal) Act 2018 (EUWA) to revoke the existing legislation implementing the BTC Directives and to deal with enforcement of the new directly applicable Regulation. We understand him to mean those Directives as they apply to Northern Ireland and to be referring to section 8C powers in EUWA to implement the Northern Ireland Protocol.

Action

2.29 We have written to the Minister of State as set out below.

2.30 We are reporting this document to the House as politically important and we draw it to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

Letter from the Chair to the Minister of State for Health

We considered your Explanatory Memorandum (EM) on the above proposal at our meeting of 26 October 2022.

The domestic regulations implementing the Blood, Tissues and Cells (BTC) Directives form part of retained EU law, a body of law which the Government is reviewing. Depending on the outcome of the review, powers in the Retained EU Law (Revocation and Review) Bill may be used to make changes to the regulations. Given the weaknesses identified by the Commission in its evaluation, and the UK's input to that evaluation as an EU Member State, it seems to us likely that the domestic legislation implementing the BTC Directives ("the implementing regulations") would be identified as retained EU law that should be amended or replaced when the Government undertakes its review. Furthermore, the direction of travel proposed by the Commission—at least for blood, tissues and cells—may well be broadly in line with how the UK may have proposed amending the legislation. That being the case and given the importance of ensuring that life-saving SoHO from EU Member States remains available to UK patients, we agree that there are compelling arguments in favour of adopting an approach broadly in line with that proposed by the Commission.

The Retained EU Law (Revocation and Review) Bill includes a sunset mechanism under which retained EU law in this category would be automatically revoked on 31 December 2023. We note that the sunset mechanism does not apply to "Northern Ireland legislation" but that the domestic legislation implementing the BTC Directives which applies in NI does not come within that definition. Can you please set out your plans for retained EU law affecting SoHO? Also, to the extent that the implementing regulations are "relevant separation agreement law",[60] how will the Bill apply?

You identify elements of the proposal which may not be relevant to the UK as a third country, such as provisions around cooperation among Member States. In that context, can you confirm that the provisions on cooperation—including joint inspections, access to the SoHO Platform and membership of the SoHO Coordination Board—would be applicable to NI? How likely is it that delegations of inspectors from EU Member States would have the right to inspect Northern Irish SoHO establishments?

You also note in your EM that the scope of the proposed Regulation is broader than the BTC Directives. Are you satisfied that the entirety of the proposed Regulation should apply automatically in NI? We are concerned that the broader scope inevitably creates potential difficulties for NI if GB does not adopt a similar approach. We look forward to receiving a summary of the outcome of your assessment of the broader scope once complete.

60 Within the meaning of section 7(C)3 of the European Union (Withdrawal) Act 2018.

Finally, the Government helpfully sets out how the Commission's proposal interacts with two of the common frameworks adopted to support policymaking across the UK following the UK's withdrawal from the European Union. We would welcome information from you as to the stage at which intra-UK discussions have reached in responding to the policy implications of the draft Regulation.

We look forward to a response to our queries by 7 December 2022.